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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,314	12/31/2003	Michael W. McLane	McLane	4050

7590 01/31/2007

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EXAMINER	
CHUI, MEI PING	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,314	MCLANE, MICHAEL W.	
	Examiner	Art Unit	
	Helen Mei-Ping Chui	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/31/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/749314 filed on 12/31/2003. Claims 1-12 are presented for examination on the merits.

Information Disclosure Statement

The information disclosure statement filed 12/31/2003 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b) that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Carruthers (US Patent Application Publication Number: US 2002/0115,648 on August 22, 2002).

Carruthers reports on the efficacy of [1,2],oxazolo[4,5-b]17-α-pregna-2,4-dien-20-yn-17-β-ol, an ethisterone derivative known as danazol, to effectively treat for the symptoms associates with hypogonadism in men and the male menopause by a pharmaceutical composition comprising low doses of danazol; or in conjunction with low doses of testosterone (page 1: paragraph 1; paragraph 14, line 1; page 2, paragraph 30). Therefore, instant claim 1 is anticipated.

Carruthers also teaches that the effective dosage of danazol can be administered to the patient orally daily in the form of a capsule or transdermally, for examples (page 3: paragraph 50, line 6-8; paragraph 51). In addition, the therapeutically effective amount of said dosage for treating hypogonadism in men described therein is between 25-100 mg per day (page 3: paragraph 3, line 4), which danazol can be in a pharmaceutically acceptable medicament in a dosage form of 25, 50, 75 or 100 mg (page 2: paragraph 30, line 3) or may be administered with a suitable carrier or excipient (page 3: paragraph 50, line 8-9). In the case of oral administration of danazol, Carruthers found that low doses of danazol three times a day is effective for the treatment of hypogonadism in men (page 3: paragraph 52, line 10-15; paragraph 54, line 15-16). The examiner interprets the administration of low doses of danazol transdermally (page 3: paragraph 50, line 8), described by Carruthers, is a form of topical delivery system that can be used to treat hypogonadism in men.

Carruthers therefore anticipated the combination of the pharmaceutical composition in the form of an oral (a capsule) dosage (instant claims 3 and 4) containing 25-100 mg of danazol as active ingredient in each oral unit dosage (instant claims 5 and 6) administered three times daily (instant claims 7 and 8). Carruthers also anticipated that low doses of danazol can be delivered transdermally (instant claim 9) or with a suitable carrier or excipient into a patient's body (instant claim 10). Additionally, danazol is known to commercially available (as Danocrine in U.S.) in vary dosages in a form of capsule (see: home website of Sanofi Pharmaceutical). Each capsule contains danazol as active ingredient and benzyl alcohol, gelatin, lactose, magnesium stearate, parabens, sodium propionate, starch and tarc as inactive ingredients (page 1: paragraph 11, line 4-8). Therefore, instant claim 2 is anticipated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description of the Invention

Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of

the claimed invention. Specifically, applicant disclosed a matrix for delivering danazol, but not norgestrol or 2-methoxyestradiol. In claims 11 and 12, applicant claims norgestrol and 2-methoxyestradiol respectively. Since there is no teaching or work example provided in the specification that norgestrol or 2-methoxyestradiol as active ingredients in said pharmaceutical composition for treating hypogonadism in adult male. Therefore, it would not reasonably convey, at the time the application was filed, to one skilled in the relevant art that the inventor had possession of the claimed invention.

Scope of Enablement of the Invention

Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of treating hypogonadism in the adult male which comprises administering to the person an effective dosage of danazol (see page 5 of specification, the section in Detailed Description of the Invention and below), does not reasonably provide enablement for the method of treating hypogonadism adult male utilizing norgestrol and 2-methoxyestradiol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

An analysis of whether the scope of a particular claim(s) is actually supported by the disclosure in a patent application requires a determination of whether the disclosure, at the time of filing, contained sufficient information regarding the subject matter of the claim at issue so as to enable one skilled in the pertained art to use the claimed invention

without undue experimentation. *In re Wands*, 8 USPQ 2d 140 (Fed. Cir. 1988). Therefore, the test of enablement is not whether experimentation is necessary, but rather, if experimentation is in fact necessary, whether it is reasonably considered to be undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). Determining the issue of enablement with respect to a claim is a question of law based on underlying factual findings. *In re Vaeck*, 20 USPQ 2d, 1444 (Fed. Cir. 1991). More particularly, there are many factors to be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and whether any necessary experimentation is reasonably considered to be "undue". See *In re Wands* at page 1404. MPEP § 2164.01(a). The court in *In re Wands* set forth the following factors to be considered, which included, without limitation, the: 1. scope or breadth of the claims; 2. nature of the invention; 3. relative level of skill possessed by one of ordinary skill in the art; 4. state of, or the amount of knowledge in, the prior art; 5. level or degree of predictability, or a lack thereof, in the art; 6. amount of guidance or direction provided by the inventor; 7. presence or absence of working examples; and 8. quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure.

The specification of the instant invention merely discloses, without more, that the composition of the instant claims 11 and 12 are capable of effectively treating hypogonadism in adult male. Since the nature of the instant invention is directed to the method of treating hypogonadism in adult male by danazol as an active ingredient in a pharmaceutical composition. However, in the instant claims 11 and 12, applicant is

purporting to treat hypogonadism in the adult male by using norgestrol and 2-methoxyestradiol.. As a result, the said compositions in the instant claims 11 and 12 which norgestrol and 2-methoxyestradiol can also effectively treat hypogonadism in adult male based on the findings from danazol are broader in scope than the enabling disclosure.

A high degree of unpredictability, not to mention a great deal of uncertainty in hormone deficiency therapy, existed in the state of the prior art regarding the aspects of bioavailability, heptotoxicity, effectiveness in treating male hypogonadism, as well as their adverse effects. Since a great deal of uncertainty and because there was an low level or degree of predictability in the art, the Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in claims 11 and 12 in order for the application to be enabled with respect to the full scope of the claimed invention.

The specification also fails to provide scientific data and working embodiments with respect to the composition in the instant claims 11 and 12, as well as the corresponding methods of effectively treating hypogonadism in the adult male. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the composition and corresponding method of the instant claims do in fact effectively treating hypogonadism in adult male.

It is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the method of

treating hypogonadism in the adult male which comprises administering to the person an amount of norgestrol (claim 11) or 2-methoxyestradiol (claim 12), that one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said composition and method would actually treat hypogonadism in adult male.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected 35 U.S.C. 112, second paragraph, because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "parenthesis" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481

(Bd. App. 1949). In the present instance, claim 11 and 12 recite the broad recitation, a therapeutic similar to danazol in its efficient displacement of bound testosterone from SHBG in the hypogonadism male, and the claim also recites norgestrol (instant claim 11) and 2-methoxyestradiol (instant claim 12) which are the narrower statement of the range/limitation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang or Cecilia Tsang can be reached on 571-272-0811 and 571-272-0562, respectively. The fax phone number for the organization where the application or proceeding is assigned is 571-273-9078.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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